REMARKS

Drawings:

The Examiner states that the instant specification does not comply with 37 C.F.R. § 1.84(U)(1) because drawings contained on multiple sheets, which are intended to form one complete view, must be identified by the same number followed by a capital letter.

In response, Applicants submit formal drawings herewith, having correct numbering of drawing sheets.

Specification:

The Description to the drawings has been changed accordingly as set forth above. Figure 1 has been renumbered as Figures 1A –1B, Figure 2 has been renumbered as Figures 2A-2D, and Figure 3 has been renumbered as Figures 3A-3MMM.

Hyperlinks:

Examiner objected to the disclosure as containing embedded hyperlinks and/or other browser-executable code.

In response, Applicants have deleted all hyperlinks from the specification, as indicated above by the replacement paragraphs.

Objection to Claim 4:

Examiner objected to claim 4 for not in compliance with the requirement for Sequence Identifiers. Correction is therefore made.

Rejection under 35 USC §101 and §112, 1st paragraph:

At page 4 of the Office Action, the Examiner has rejected claims 4, 9, and 24-26 under 35 U.S.C.§101 and §112, 1st paragraph. In summary, the Examiner has stated that the claimed isolated nucleic acid molecules lack a specific and substantial utility or a well-established utility and, consequently, one skilled in the art would not know how to use the claimed invention.

The Examiner stated that "amino acid structure cannot necessarily predict the function of the protein: 'Knowing the protein structure by itself is insufficient to annotate a number of

functional classes and is also insufficient for annotating the specific details of protein function'" (see Office Action page 6, first paragraph).

Further, the examiner on page 7 of the Office Action stated that the utilities recited in the specification of the present invention are not specific and substantial, because the specification does not disclose any diseases or conditions known to be associated with the transporter proteins. Therefore, the examiner concluded that the use of the molecules as targets for identifying therapeutic agents or for drug screening or other biological assays does not identify or confirm a "real world" context use.

Applicants respectfully traverse this rejection based on the following remarks.

In contrast to the Examiner's assertions, the claimed isolated nucleic acid molecules, such as SEQ ID NOS:1 and 3, that encode a specified amino acid sequence, SEQ ID NO:2, and methods of making and using such nucleic acid molecules have several uses that meet the requirements of 35 U.S.C.§101 and the first paragraph of 35 U.S.C.§112. These, as well as the accepted state of the art view that such molecules have uses within the commercial marketplace in the drug development cycle, since they encode previously unidentified members of important pharmaceutical targets, establishes the utility of the claimed invention.

The utility requirement of a claimed invention requires that an invention must have a specific, substantial and credible utility. These requirements are defined in broad terms in cases such as *Brenner v. Manson,* 148 USPQ 689 (S. Ct. 1966) and the recently adopted Utility Guidelines from the USPTO.

The Examiner stated, "amino acid structure cannot necessarily predict the function of the protein." However, besides the sequence comparison, the specification also provides a list of Prosite determination, and Hummer domain determination resulting in significant statistic values, to classify the protein of the present invention as transporter family.

The Examiner further stated that the present invention failed to disclose any properties of the present invention, SEQ ID NO: 2 that associated with any disease state. However, such a requirement substantially conflicts with the decision made by the CCPA.

The CCPA in *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980), clearly accepted a showing of less than a specific therapeutic use of a claimed chemical compound as satisfying the utility requirement.

The CCPA held that where a claim does not provide evidence of pharmacological activity of a claimed compound, although it does not establish a specific therapeutic use, manifests a practical utility because knowledge of pharmacological activity is beneficial to the public in that it makes faster and easier for medical researchers to combat illnesses. Nelson v. Bowler, 206 USPQ 881 (CCPA 1980).

The notion that a recognized valuable addition to even entry points of the drug discovery cycle advances the art sufficient to establish a "usefulness" of a claimed invention should not be ignored. Similar to the *Nelson* case, the present invention, which is drawn to isolated nucleic acid molecules that encode a transporter protein (SEQ ID NO: 2), has useful value in the drug discovery process even though the molecule may not be associated with a specific treatment and/or diagnosis of a particular disease. According to *Nelson*, the present invention provides sufficient knowledge and information that is beneficial to the public, and provides sufficient guidance for researchers to use the claimed subject matter to develop disease treatments and/or diagnostics. It is well recognized that transporters are the most important targets for drug action (pages 1-14 of the specification). The public disclosure of a new member of this family through the patenting process clearly advances the art and augments the capabilities of biomedical researchers to combat illnesses.

The utility rejection raised by the Examiner also conflicts with the case *Juicy Whip v. Orange Bang* (Fed. Cir. 1999). *Juicy Whip* held that, in order to violate the utility requirement, an invention must be "totally incapable of achieving a useful result." The polypeptides and encoding nucleic acid molecules of the present invention are well known in the art to be valuable drug targets and therefore have readily apparent commercial utilities, such as for screening potential drug compounds, producing antibodies, developing hybridization probes and primers, etc. In addition to the uses disclosed in the specification and discussed herein for the polynucleotides of the present invention, other utilities are readily apparent to one of ordinary skill in the art based on the observed tissue specific expression patterns. Specifically, the proteins/nucleic acid molecules of the present invention are expressed in prostate and testis. Thus, for example, the proteins/nucleic acids of the present invention are commercially useful for developing therapeutic agents for treating diseases affecting these tissues. Therefore, the present invention is not "totally incapable of achieving a useful result." Instead, it is useful.

The specification and figures show that the protein of the present invention has functional domain of calcium channel. The disclosure of the function of the transporter is sufficient. Such a function is quite specific for transporter proteins and differentiates them from other proteins. As such, this function is specific enough to define a use for novel transporter proteins and transporter-encoding nucleic acid molecules in the drug discovery process.

As stated in the Background section of the specification, members of the transporter protein family, particularly those related to the sodium/calcium channel subfamily, which plays a role in facilitate sodium/calcium transportation. Novel transporter proteins/nucleic acids are commercially useful for developing therapeutics/diagnostics for these and other pathologies. Thus, there is overwhelming evidence in the art to support the utility of novel transporter proteins and encoding nucleic acid molecules, particularly those related to calcium channel protein. Not all nucleic acid molecules, and actually a very limited number, of the 3 billion bases that make up the human genome will encode a protein for these and the other disclosed uses. These uses are quite specific for the transporter family of proteins, even though each member may play a somewhat different role in cellular responses and pathologies. Even though each member may have a somewhat different role in biology and disease, each is a specific composition of matter having substantial, specific and credible uses that the vast majority of other isolated nucleic acid molecules do not possess.

By placing a new member of the transporter protein family into the public domain through the patenting process, the present invention is not only a clear advancement over the prior art (a newly discovered protein/gene) but also enables significant advancement in medicine and further discovery. The Utility requirement cannot be used to contradict the reasons for the patent system, to encourage early disclosures of inventions so that others can benefit from, improve upon, and further develop such inventions. This is particularly important in medicine, wherein early disclosure of key inventions (such as new transporter proteins and encoding nucleic acid molecules) is needed to facilitate the early development of new therapies and diagnostics to treat illnesses.

The grant of a patent to the claimed isolated nucleic acid molecule and the resultant disclosure of the nucleic acid and protein sequences to the public will certainly shorten the process for medical researchers to discover other novel uses for the present transporter-encoding nucleic acids. One example disclosed in the specification is that the present nucleic acid

molecules can be used to produce protein targets for identifying agents that bind to the protein targets and modulate protein function. Such agents can be used to precisely determine which biological and pathological processes the protein is involved in. Furthermore, such agents that bind to a protein target and modulate cell signaling may subsequently be developed and refined for use in mammalian therapeutic applications. All of this later discovery and refinement will be done using the presently claimed material. These uses are clearly commercial and substantial uses that are specific for a very limited number of proteins/nucleic acid molecules.

In addition to serving as targets for developing molecular probes and therapeutic agents, the disclosed uses of the claimed nucleic acid molecules as probes, primers, and chemical intermediates, particularly in biological assays, is sufficient to satisfy the requirements of 35 USC §101 and §112. The claimed invention is directed to nucleic acid sequences that encode a transporter protein with a specified amino acid sequence (SEQ ID NO: 2), such as SEQ ID NOS: 1 and 3. Exemplary uses of the nucleic acid sequences are clearly recited in the specification on, for example, pages 38-62. Among the examples, the nucleic acid molecules are useful as hybridization probes for messenger RNA molecules, transcript/cDNA molecules, genomic DNA, and variants thereof. An expression vector comprising the nucleic acid sequences can be made that expresses the transporter protein. Such uses are specific for the claimed nucleic acid molecules, and the products of such uses will be clearly different (and hence specific for the claimed molecules) than what would be produced using a different nucleic acid molecule for the same purpose.

In view of law and fact, the utility standard interpreted by the USPTO guidelines is too high. The disclosure of activity of the expressed polynucleotide is not required by any statute or case law interpreting the utility requirement of Section 101, and the enablement requirement of Section 112, first paragraph. The commercial value of a gene that encodes a previously unidentified member of the transporter protein family, members of which are well known in the art to be commercially valuable drug targets, should be sufficient to satisfy the utility requirement.

Rejections under 35 USC §112, 2nd paragraph:

The Examiner rejected claims 6, 8, 24 and 27-29 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejected claims 6 and 8 for being vague and indefinite because they depend from cancelled claim 5. Claim 6 was withdrawn and now canceled. Claim 8 was inadvertently omitted by Applicants and amendment is made. Thus the rejection is moot.

The Examiner stated that claim 24 is vague and indefinite for recitation of a "polypeptide", which is produced by the host cell of claim 9.

The Examiner stated that claim 24 recites the limitation "host cell" in claim 9. Claim 9 was inadvertently replaced by claim 8. Amendment has been made, thus, the limitation of "host cell" is provided with antecedent basis. Further the Examiner stated that claim 24 recites the limitation "the peptide" in reference to "said polypeptide". Applicants respectfully disagree with the reject, because "the peptide" language is not found in the claim.

Claims 24 27-29 are dependent from claim 4 part (d), which is directed to a complementary nucleic acid sequence. The examiner stated that it is unclear how one would be able to produce a polypeptide from the complementary sequences. In clarifying the claim, but not narrowing the claim, Applicants have amended claim 24 which specifically recited "a polypeptide comprising SEQ ID NO: 2" and "a nucleic acid molecule that encodes said polypeptide." The said polypeptide is SEQ ID NO: 2.

Applicants believe the amendment and the explanation satisfy the requirement under 112, 2nd paragraph. Therefore, the rejection to claims 6, 8, 24 and 27-29 should be withdrawn.

Conclusions

Claims 4, 8-9, and 24-29 are currently pending.

In view of the above remarks and amendments, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,

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